REMARKS/ARGUMENTS

Claims 1-29 are pending in the application. Claims 1-5 and 21-29 have been rejected under 35 U.S.C. Section 103(a). Claims 1, 2, and 24 - 29 have been amended. Claims 6 - 20, formerly withdrawn from consideration, have been cancelled without prejudice to the filing of a divisional application. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

Telephone Interview. The Applicants thank the Examiner for the telephone interview of August 7, 2006, during which the prior art reference to Osorio and the present invention were discussed. In accordance with this discussion, the Applicants have amended the claims. Reconsideration of the claims in view of the amendments is respectfully requested.

Claim Objections

Claims 1, 2, and 24 - 29 have been objected to for various informalities. The claims have been amended to correct these deficiencies, and the Applicants respectfully request that the objections to the claims be withdrawn.

103 Rejection

Claims 1 - 4, 21 - 24, 28, and 29 have been rejected under 35 U.S.C. Section 103(a) as unpatentable over Osorio, U.S. Patent 6,341,236 in view of Adkins, U.S. Patent 5,928,272. Claims 5 and 25 - 27 have been rejected as unpatentable over Osorio in view of Adkins, and further in view of Lo, U.S. Patent 5,738,104.

Claim 1, as amended, recites a method for non-invasive detection of a vagus nerve stimulation signal. The method includes the steps of applying external electrodes to a patient in proximity to an implanted vagus nerve stimulator. A detected vagus nerve signal is detected, amplified, filtered, and then prolonged to allow sampling of the vagus nerve

stimulation signal and to trigger sampling of at least one other physiological signal to allow for monitoring the effect of the vagus nerve stimulation on the at least one other physiological signal. The present invention, therefore, provides a non-invasive method for determining when a vagus nerve stimulation signal has been applied, and to trigger other monitoring equipment based on this detected signal. Therefore, the reaction of various physiological parameters to a vagus nerve stimulation signal can be monitored externally, without the need to implant additional devices into a patent. Furthermore, the method of the present invention can be used in conjunction with any vagus nerve stimulation device.

The Osorio reference discloses an automatic neurostimulation device. The stimulation device comprises a sensor 15 for sensing characteristics of the heart rate, and information derived from the sensor 15 is used to determine whether vagus nerve stimulation is adversely affecting the heart. The sensor, as discussed at column 4, lines 53 - 65, is implanted at or near the heart, and communicates with the sensor by a cable 17, or, in the alternative, can communicate through telemetry, e.g. through radiofrequency signals (column 5, lines 1 - 5) with the implanted sensor device. Alternatively, as discussed at column 11, lines 11 - 17, a signal generator and pacemaker may be combined in a single implanted device. Referring to Figures 9 and 10, and also to column 11, line 18 through column 12, line 3, the signal that is monitored by this device is an EKG signal.

Adkins discloses an implanted device for controlling seizures in an epileptic patient. Referring to Fig. 1, the device includes a generator 25 equipped with sensing electrodes for measuring electrical impulses indicating cardiac activity, and an array of stimulating electrodes 15 are connected to the vagus nerve signal. An electrical signal 47 indicative of cardiac activity (such as an EKG or ECG signal) is monitored (see column 6, lines 54 through 58; column 9 lines 7 - 11). The device monitors a time rate of change of the patient's heart rate from cardiac activity to determine when to apply a stimulus to the cranial nerve.

Osorio, therefore, requires either an implanted device or telemetry communications to an external sensor. Osorio neither teaches nor suggests that a vagus nerve stimulation signal can be detected with the use of external electrodes. Adkins, similarly, includes a monitoring system that is implanted, and that is intended to monitor cardiac activity. Adkins neither teaches nor suggests monitoring the vagus nerve stimulation signal using external electrodes.

Neither reference, therefore, discloses a system for applying external electrodes to detect and monitor a vagus nerve stimulation pulse as recited in claim 1. Both systems require either that the monitoring be internal, or that communications be provided through RF communications, thereby requiring that specific and mating components be provided internally and externally. Furthermore, these devices specifically monitor cardiac activity. They do not directly monitor a vagus nerve stimulation signal. Additionally, these devices do not monitor a vagus nerve stimulation signal in order to trigger the monitoring of other physiological signals, such as cardiac activity. At best, these devices filter cardiac monitoring to obtain a vagus nerve signal.

In view of these distinctions, these references cannot be combined to provide the invention as recited in claim 1, as amended, or associated dependent claims 2 - 5 and 21 - 29. Therefore, the Applicants respectfully request that the rejection of claims 1 - 5 and 21 - 29 under 35 U.S.C. Section 103 be withdrawn.

The Commissioner is authorized to charge any fees under 37 CFR § 1.17 that may be due on this application to Deposit Account 17-0055. The Commissioner is also authorized to treat this amendment and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

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